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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/095,536	06/10/1998	JOHN A. KINK	OPHD-03282	9749
23535	7590	09/19/2006	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			HISSONG, BRUCE D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/095,536	<b>Applicant(s)</b> KINK, JOHN A.	
	<b>Examiner</b> Bruce D. Hissong, Ph.D.	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### **Formal matters**

1. Applicant's response to the office action mailed on 11/25/2005, including amended claims, was received on 3/2/2006 and has been entered into the record.

2. The Applicant's amendments to the claims received on 3/2/2006 cancelled claims 7-12, 15-18, and 34-48. Therefore, claims 49-51 are currently pending and are the subject of this office action.

3. The text of those sections of Title 35, U.S.C. not included in this action can be found cited in full, in the previous office action mailed on 4/6/2005.

4. Prosecution on the merits of this application is reopened on claims 49-51, considered unpatentable for the reasons indicated below.

### **Claim Rejections - 35 USC § 102**

Claims 49-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Skurkovich *et al* (US 5,888,511 – cited in a previous office action mailed on 8/23/2001). The claims of the instant invention are drawn to a method of treatment for mammals having symptoms of sepsis, wherein said method comprises administering a composition comprised of anti-tumor necrosis factor (TNF)- $\alpha$ , anti-interleukin (IL)-6, and anti-interferon (IFN) antibodies. The claims are further drawn to the method for treating sepsis wherein the antibodies are polyclonal, and a therapeutic composition for treating sepsis, wherein the composition comprises anti-TNF- $\alpha$ , anti-IL-6, and anti-IFN antibodies.

Skurkovich *et al* teaches a pharmaceutical composition comprised of a plurality of at least two of several components, which include an antibody to gamma IFN, an antibody to TNF, and an antibody to IL-6 (see claims 3 and 9). Although Skurkovich *et al* is drawn to compositions and methods for treating autoimmune disease, including AIDS, and does not

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specifically recite a method of treating a mammal having the symptoms of sepsis, it is noted that the instant specification, on page 5 defines "symptoms of sepsis" as including but not limited to symptoms such as fever and organ dysfunction. Fever is a known symptom of AIDS ([http://www.webmd.com/hw/hiv\\_aids/hw151445.asp](http://www.webmd.com/hw/hiv_aids/hw151445.asp)), as is organ dysfunction (e.g. dysfunction of the immune system). Thus, by teachings compositions and methods for treating AIDS, Skurkovich *et al* teaches compositions and methods for treating symptoms of sepsis, and therefore meets the limitations of claim 49. Skurkovich *et al* also teaches that the antibodies used for methods and compositions for treatment of AIDS can be polyclonal (column 15, lines 2-9), thus meeting the limitations of claim 50. Finally, as noted above, Skurkovich *et al* does not specifically recite a composition for use with a mammal having symptoms of sepsis. However, the components of the composition of claims 3 and 9 of Skurkovich *et al* are the same as that of claim 51 of the instant application. Therefore the disclosure of Skurkovich *et al* anticipates claim 51, regardless of the intended use of either the composition taught by Skurkovich *et al*, or of the composition of claim 51 of the instant application. Finally, it is noted that the WebMD citation is not being used in a grounds of rejection, but to point out that which is well-known in the art regarding the symptoms of AIDS.

**Conclusion**

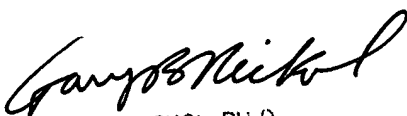
No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH  
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GARY B. NICKOL, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600